

various aspects of certain claims. See *id.* at pages 2 to 5. The statement of the bases for the rejection at pages 2 to 5 of the Final Action appears to be essentially unchanged from the bases set forth in the Office Action that was mailed December 14, 2001 (Paper No. 7). The Examiner discusses applicant's prior arguments at pages 11 to 14 of the Final Action.

Applicant respectfully traverses the rejection. Rather than repeat all of the prior arguments, applicant incorporates by reference all of the prior arguments presented in the Amendment that was filed on March 14, 2002 (March 2002 Amendment). Applicant respectfully asserts that the Examiner has not adequately addressed those arguments.

Independent claim 115 recites a probe that comprises "an addressable support-specific portion located between the primer-specific portion and the target-specific portion." Independent claims 52 and 60 recite that "at least one probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion." Independent claim 71 recites that "at least one second probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion."

The Examiner first contends that Barany PCT discusses a probe set that includes two probes that are suitable for ligation together and that each includes a target specific portion and an addressable array portion. See *id.* at pages 2 to 3. The Examiner further contends that the terminal nucleotides of the addressable array portions of each probe can inherently function as a primer-specific portion. See *id.* at pages 4 to 5.

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The Examiner then contends that, "with regard to the orientation of the primer region and the addressable region, it is noted that in an oligonucleotide, these terms represent intended use limitations and do not structurally effect the oligonucleotide." See *id.* at page 4. The Examiner then illustrates his position by showing that an exemplary nucleotide split into two or three separate portions is the same nucleotide irrespective of the intended properties of each portion. See *id.* The Examiner further states that "any region of any oligonucleotide is inherently and necessarily capable of function as a primer target region, or as an addressable region or as a target specific region, which specificity is solely dependent upon experimental selection of the appropriate primer, capture probe or target." See *id.* at pages 4 to 5.

Applicant respectfully asserts that the Examiner has not established that Barany PCT anticipates any of the present claims. As discussed above, all of applicant's independent claims recite a probe that comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion. Thus, as emphasized in the March 2002 Amendment, each of those claims includes a probe that comprises three specific portions that have three different functions, and those three specific portions are arranged in a particular order. Moreover, applicant previously asserted that the three specific functions require the three specific portions to have particular structure. Thus, the three specific portions do affect the structure of the probe.

In response, the Examiner continues to fail to contend that Barany PCT actually shows or even suggests a probe that has the three specific portions with the three different functions according to the present claims. Rather, the Examiner reiterated the

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argument that the claimed ordered structure of the probes "is simply intended use language [that does] not impose any particular sequence requirements and Barany teaches specific probes which inherently meet the structural requirements"1

The Examiner fails to establish anticipation by inherency. To find anticipation by inherency, the PTO must establish that the prior art document necessarily includes the claim element in question.

Here, the Examiner agrees that Barany PCT shows a probe with only two specific portions with two different functions. Specifically, the Examiner contends that Barany shows a probe with an allele specific portion and an addressable sequence on the 5' end that hybridizes to a complementary sequence on an addressable array. See Barany PCT at page 12, lines 25 to 29. The Examiner then contends that Barany PCT need not actually show or even suggest the third specific portion, a primer-specific portion, as set forth in the present claims. The Examiner reaches that conclusion by contending that primers can be designed for all oligonucleotides, and thus, the addressable sequence on the 5' end of the Barany PCT probe is also capable of being a primer-specific portion.

¹ When responding to applicant's prior response to the two different anticipation rejections, the Final Action fails to distinguish between the different rejections over Barany PCT and Barany US. If the two anticipation rejections are maintained, applicants respectfully request that the Examiner differentiate between the two rejections. Also, the Final Office Action at page 11 mentions an alleged argument by applicant that Barany (unspecified) does not teach a probe set where the probes are suitable for ligation together. The Examiner fails to cite a particular passage from the March 2002 Amendment concerning this alleged argument. Applicant asserted that Barany PCT and Barany US both failed to teach the claimed invention, including all elements of the claims. It is not clear what the Examiner is addressing in his argument concerning a probe set suitable for ligation together.

The fact that someone could design primers that hybridize with the addressable sequence in Barany PCT does not convert Barany PCT into a teaching of a probe comprising the three specific structural portions with the three different functions. The Examiner presents no reason why one skilled in the art would design a primer specific for the addressable sequence in the Barany PCT probe. In fact, Barany discusses hybridizing the ligation product, which includes the addressable sequence, directly to an array without amplification of the ligation product. The Examiner continues to provide no reason why one skilled in the art would design the addressable sequence of the Barany PCT probe to also serve as a primer-specific portion, since there is no suggested amplification of the ligation product in Barany PCT. Absent such a reason, it is unclear why the Examiner contends that one skilled in the art would design the Barany PCT probe to include an addressable support-specific portion between a primer-specific portion and a target-specific portion.

Thus, the Barany PCT probe does not necessarily include a primer-specific portion having a given function, an addressable support-specific portion having a different function, and a target-specific portion having a third different function. The particular order of those portions and their functions require those three portions and the probe to have particular structure. Accordingly, Barany fails to teach, inherently or otherwise, a probe comprising the three specifically claimed portions with the three specific functions.

For at least these reasons, the Examiner has failed to establish that Barany PCT would have shown or suggested claims 52, 60, 71, and 115, and all claims dependent from those claims. Thus, applicant need not address the Examiner's contentions

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concerning the other limitations of those claims. By not addressing those contentions, applicant in no way acquiesces to those contentions.

In the March 2002 Amendment, applicant noted that dependent claims 53, 62, and 73 recite kits that further comprise one or more primers in addition to at least one probe set. Applicant asserted in that amendment that the Examiner failed to assert that Barany PCT showed primers in addition to probes. In the Final Office Action, the Examiner failed to address that assertion and continues to reject those claims as allegedly being anticipated by Barany PCT. Thus, the Examiner continues to fail to establish that Barany PCT shows or suggests claims 53, 62, and 73 for at least this additional reason. If this rejection is maintained, applicant respectfully requests that the Examiner further explain his position.

Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of certain claims in view of Barany PCT.

Rejection In View of Barany US

The Examiner rejected claims 52 to 63, 69 to 79, 85, 86, 115 to 117, and 120 to 129 under 35 U.S.C. § 102(a) and (e) as allegedly being anticipated by US Patent No. 6,027,889 (Barany US). See Action at page 5. The Examiner cites various text of Barany US as allegedly showing various aspects of certain claims. See *id.* at pages 5 to 6.

The statement of the bases for the rejection at pages 5 to 7 of the Final Action appears to be essentially unchanged from the bases set forth in Paper No. 7. The Examiner discusses applicant's prior arguments at pages 11 to 14 of the Final Action.

Applicant respectfully traverses the rejection. Rather than repeat all of the prior arguments, applicant incorporates by reference all of the prior arguments presented in the March 2002 Amendment. Applicant respectfully asserts that the Examiner has not adequately addressed those arguments.

Independent claim 115 recites a probe that comprises "an addressable support-specific portion located between the primer-specific portion and the target-specific portion." Independent claims 52 and 60 recite that "at least one probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion." Independent claim 71 recites that "at least one second probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion."

Applicant respectfully asserts that the Examiner has not established that Barany US anticipates any of the present claims. As discussed above, all of applicant's independent claims recite a probe that comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion. Thus, as emphasized in the March 2002 Amendment, each of those claims includes a probe that comprises three specific portions that have three different functions, and those three specific portions are arranged in a particular order. Moreover, applicant previously asserted that the three specific functions require the three specific portions to have particular structure. Thus, the three specific portions do affect the structure of the probe.

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Apparently addressing both anticipation rejections involving Barany PCT and Barany US, the Examiner again does not assert that Barany US teaches or even suggests the claimed structural order of the probes. Rather, the Examiner relies upon his assertion that such elements are intended use limitations that need not be considered in view of the alleged inherent characteristics of the Barany US probes.

In the March 2002 Amendment, applicant provided specific reasons why the Examiner had failed to establish that one skilled in the art would have rearranged the structures in Barany US to meet the limitations of the claims. See, e.g., March 2002 Amendment at the paragraph bridging pages 15 and 16, and at page 16, last paragraph, to page 18, last full paragraph. The Examiner did not specifically address any of those detailed assertions. Rather, the Examiner apparently contends that such assertions need not be addressed. Applicant maintains all of those assertions and asserts that the Examiner continues to fail to establish anticipation of any of the pending claims in view of Barany US for at least those reasons.

In addition to the prior bases for the rejection in Paper No. 7, the Examiner asserts that "Barany expressly teaches sets of six probes with identical sequences at the 5' end (see column 51, lines 25-29)." Final Action at page 7. The Examiner also asserts that "Barany expressly teaches the use of sets of probes (see column 45, tables 6 and 7)." *Id.*

First, it is not clear what specific claims and claim elements the Examiner is addressing with the assertion that "Barany expressly teaches the use of sets of probes" Without an express statement of what is being addressed, it is unclear how to respond. Thus, applicant traverses that statement, and if the statement is

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maintained, also respectfully requests that the Examiner expressly apply the statement to a particular claim and claim element. Applicant also notes that the two tables cited by the Examiner list **primer** sets, not probe sets as alleged by the Examiner. Thus, it is further unclear how the Examiner considers such tables pertinent.

Second, the Examiner's statements concerning Barany US's alleged teachings concerning "six probes with identical sequences" appears to address claims 120 to 129. Claims 120, 122, 124, 126, and 128 recite that the at least one probe set comprises at least two different probe sets for detecting at least two different target sequences. At least one probe in a first probe set comprises a primer-specific portion, a target-specific portion that hybridizes to a portion of a first target sequence, and an addressable support-specific portion that is specific for the first target sequence. At least one probe in a second probe set comprises a primer-specific portion, a target-specific portion that hybridizes to a portion of a second target sequence, and an addressable support-specific portion that is specific for the second target sequence. The primer-specific portions of the probes have identical sequences.

Thus, the two probes comprise identical primer-specific sequences, but comprise different addressable support-specific portions that are specific to two different target sequences and different target-specific portions that hybridize to two different target sequences. In contrast, the six probes of Barany US that were discussed by the Examiner have only a gene specific 3' region and a 5' region corresponding to one of two sets of universal primers. See Barany US at column 50. The Examiner fails to explain how that portion of Barany US would have taught or suggested two different

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probes that further comprise different addressable support-specific portions that are specific to two different target sequences.

Thus, for at least this additional reason, the Examiner has failed to establish that Barany US would have shown or suggested claims 120, 122, 124, 126, and 128.

Claims 121, 123, 125, 127, and 129 recite that the at least one probe set comprises at least six different probe sets for detecting at least six different target sequences. At least one probe in each of the six different probe sets comprises a primer-specific portion, a target-specific portion that hybridizes to a portion of one of the at least six different target sequences, and an addressable support-specific portion that is specific for the one of the at least six different target sequences. The primer-specific portions of each of such probes of the at least six different probe sets have identical sequences.

Thus, the at least six different probes comprise identical primer-specific sequences, but comprise different addressable support-specific portions that are specific to the at least six different target sequences and different target-specific portions that hybridize to the at least six different target sequences. In contrast, the six probes of Barany US that were discussed by the Examiner have only a gene specific 3' region and a 5' region corresponding to one of two sets of universal primers. See Barany US at column 50. The Examiner fails to explain how that portion of Barany US would have taught or suggested six different probes that further comprise different addressable support-specific portions that are specific to six different target sequences.

Thus, for at least this additional reason, the Examiner has failed to establish that Barany US would have shown or suggested claims 121, 123, 125, 127, and 129.

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For at least these reasons, the Examiner has failed to establish that Barany US would have shown or suggested claims 52, 60, 71, and 115, and all claims dependent from those claims. Thus, applicant need not address the Examiner's contentions concerning the other limitations of those claims. By not addressing those contentions, applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of certain claims in view of Barany US.

Rejection In View of Barany PCT and Xu

The Examiner also rejected several claims under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barany PCT in view of Xu et al., Tetrahedron Lett., 38(32):5595-5598 (1997) (Xu). See Action at page 7. The Examiner cited Barany PCT for the reasons discussed in the prior rejections and stated that Barany PCT did not teach use of tosylated or iodate oligonucleotides for ligation. See *id.* (Certain dependent claims specifically recite that "the 5' thymidine leaving group is tosylate or iodide.") The Examiner contended that Xu discussed tosylated and iodate oligonucleotides for ligation. See *id.* Applicant respectfully traverses.

All of the dependent claims that specifically recite that "the 5' thymidine leaving group is tosylate or iodide" ultimately depend from one of independent claims 52, 60, 71, or 115. Thus, all of those dependent claims include all of limitations of the claims from which they ultimately depend. Above, applicant explained why the Examiner failed to establish that Barany PCT showed or would have suggested independent claims 52, 60, 71, and 115. Xu would have failed to remedy those deficiencies of Barany PCT.

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Thus, the Examiner has failed to establish that the combination of Barany PCT and Xu would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Barany PCT and Xu with respect to other limitations of certain dependent claims. By not addressing those contentions, applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of certain claims in view of Barany PCT and Xu.

Rejection In View of Barany PCT and Boyce-Jacino

The Examiner rejected claims 52 to 64, 69 to 80, 85, 86, and 115 to 117 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barany PCT in view of WO 99/66076 (Boyce-Jacino). See Final Action at page 8. The Examiner notes that he cites Boyce-Jacino as allegedly teaching a primer-specific portion to be used with the probe of Barany PCT if the anticipation rejection that relies upon the alleged inherency of such a primer-specific portion is reversed. See *id.*

The Examiner cites various text of Barany PCT as allegedly showing various aspects of certain claims. See *id.* at pages 8 to 10.

The Examiner first contends that Barany PCT discusses a probe set that includes two probes that are suitable for ligation together and that each includes a target specific portion and an addressable array portion. See *id.* at pages 8 to 9. The Examiner further contends that the terminal nucleotides of the addressable array portions of each probe can inherently function as a primer specific portion. See *id.* at page 9.

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The Examiner further contends that Boyce-Jacino "teaches embodiments of probes which teaches that the addressable or capture region can be rearranged with the primer to form a primer, capture, target binding arrangement (see pages 13-18)." See *id.* at page 10. Specifically, the Examiner quotes Boyce-Jacino as follows: "In another preferred embodiment, the capture moiety comprises a specific sequence complementary to a PCR primer or portion thereof, used to amplify a region of the template strand." See *id.*

The Examiner concludes that it would have been obvious for one skilled in the art "to utilize the rearranged primer as taught by Boyce-Jacino in the method of Barany in order to permit amplification of the template strand within the primer in a nested PCR type reaction." See *id.* The Examiner further contends that an "ordinary practitioner would have been motivated to modify the Barany primer to include a primer sequence within the capture moiety in order to permit amplification of the template strand and to permit nested amplification." See *id.* Applicant respectfully traverses the rejection.

The statement of the bases for the rejection at pages 10 to 11 of the Final Action appears to be essentially unchanged from the bases set forth in Paper No. 7. The Examiner discusses applicant's prior arguments at pages 11 to 14 of the Final Action.

Applicant respectfully traverses the rejection. Rather than repeat all of the prior arguments, applicant incorporates by reference all of the prior arguments presented in the March 2002 Amendment. Applicant respectfully asserts that the Examiner has not adequately addressed those arguments.

Independent claim 115 recites a probe that comprises "an addressable support-specific portion located between the primer-specific portion and the target-specific

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portion.” Independent claims 52 and 60 recite that “at least one probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion.” Independent claim 71 recites that “at least one second probe in each probe set further comprises an addressable support-specific portion located between the primer-specific portion and the target-specific portion.”

Applicant now addresses the Examiner’s contentions concerning applicant’s arguments. The Examiner still fails to adequately explain the alleged teaching provided by the two applied documents that would have motivated one of ordinary skill in the art to change the probe of Barany PCT to arrive at the claimed invention.

The Examiner first contends that applicant improperly presented arguments against the references individually when the rejection was based on a combination of references. Final Action at pages 12 to 13. The Examiner then contends that the motivation to modify the Barany PCT probes is “a motivation ‘in order to permit amplification of the template strand within the primer in a PCR reaction.’” *Id.* at page 13.

Applicant’s prior response properly addressed the combination and modification of the references proposed by the Examiner. In fact, the prior response directly addressed the Examiner’s failure to establish that the combined documents would have motivated one skilled in the art to modify the probe of Barany PCT by changing the

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arrangement of the Barany PCT primer to include an addressable support-specific portion between a primer-specific portion and a target-specific portion.²

The Examiner contends that the motivation to modify the Barany PCT probes was an alleged motivation to "permit amplification of the template strand within the primer in a PCR reaction." Final Action at page 12. The Examiner, however, still fails to explain where the motivation would have arisen to amplify the ligation product in Barany PCT.

As discussed in the March 2002 Amendment, Barany PCT fails to discuss amplification of the ligation products that include the ligated probe with an addressable sequence. Thus, the Examiner still fails to establish why there would have been any motivation on the part of one skilled in the art to reach to Boyce-Jacino for a teaching about amplification primers for amplifying such ligation products. The Examiner simply fails to explain why one skilled in the art would have used the alleged "rearranged primer of Boyce-Jacino in the method of Barany . . ." when Barany PCT fails to discuss any method of amplifying the ligation product that includes an addressable sequence.

When the U.S. Patent and Trademark Office makes "core factual findings in a determination of patentability, . . ." the Office "must point to some concrete evidence in the record to support [such] findings." *In re Zurko*, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). Moreover, the Office "cannot rely on conclusory statements when dealing with

² It is not clear what particular assertions in the March 2002 Amendment the Examiner considered to be attacks on individual documents. If this basis for the rejection is maintained, applicant would appreciate a more specific statement on this point. In the March 2002 Amendment, applicants disagreed with some of the Examiner's allegations concerning certain individual teachings. See that amendment, e.g., at page 23, first full paragraph, and the paragraph bridging pages 23 and 24.

particular combinations of prior art and specific claims, but must set forth the rationale on which it relies." *In re Lee*, 61 U.S.P.Q.2d 1430, 1435 (Fed. Cir. 2002).

Here, the Examiner provides neither concrete evidence on the record nor a suitable rationale why one of ordinary skill in the art would have been taught to use the alleged rearranged primer of Boyce-Jacino to amplify addressable sequences in the Barany PCT ligation product, when Barany PCT discusses no amplification of such ligation products. Moreover, the Examiner has not explained how Boyce-Jacino would have provided such motivation to modify the Barany PCT method. In fact, the Examiner still provides no evidence of record or rationale for his statement that the ordinary practitioner would have been motivated to modify the Barany PCT primer to include a primer sequence within the capture moiety. The Examiner has pointed to no such motivation in either applied document. In fact, the Examiner points to no disclosure in Barany PCT of a primer, which is used for amplifying the addressable sequence, that could be modified.

The Examiner also disagreed with applicant's assertion that Boyce-Jacino fails to suggest a probe or primer that includes "a primer, capture, target binding arrangement." See Action at page 13. Applicant continues to maintain that assertion for the reasons set forth in the March 2002 Amendment at pages 23 to 24. The Examiner's contentions fail to address those specific assertions. Rather, the comments focus solely on the primer region and the capture region.

Accordingly, the Examiner has failed to establish that the combination of Boyce-Jacino and Barany PCT would have motivated one of ordinary skill in the art to make the presently claimed probes or kits of independent claims 52, 60, 71, and 115.

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Thus, the Examiner has failed to establish that Barany PCT and Boyce-Jacino would have shown or suggested claims 52, 60, 71, and 115, and all claims dependent from those claims. Thus, applicant need not address the Examiner's contentions concerning the other limitations of those claims. By not addressing those contentions, applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of certain claims in view of Barany PCT and Boyce-Jacino.

Rejection In View of Barany PCT and Boyce-Jacino and Xu

The Examiner also rejected several claims under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barany PCT, in view of Boyce-Jacino, and further in view of Xu et al., Tetrahedron Lett., 38(32):5595-5598 (1997) (Xu). See Final Action at page 10. The Examiner cited Barany PCT and Boyce-Jacino for the reasons discussed in the prior rejection and stated that Barany PCT and Boyce-Jacino did not teach use of tosylated or iodate oligonucleotides for ligation. See *id.* (Certain dependent claims specifically recite that "the 5' thymidine leaving group is tosylate or iodide.") The Examiner contended that Xu discussed tosylated and iodate oligonucleotides for ligation. See *id.* Applicant respectfully traverses.

All of the dependent claims that specifically recite that "the 5' thymidine leaving group is tosylate or iodide" ultimately depend from one of independent claims 52, 60, 71, or 115. Thus, all of those dependent claims include all of limitations of the claims from which they ultimately depend. Above, applicant explained why the Examiner failed to establish that Barany PCT and Boyce-Jacino would have suggested independent

claims 52, 60, 71, and 115. Xu would have failed to remedy those deficiencies of Barany PCT and Boyce-Jacino.

Thus, the Examiner has failed to establish that the combination of Barany PCT, Boyce-Jacino, and Xu would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Barany PCT, Boyce-Jacino, and Xu with respect to other limitations of certain dependent claims. By not addressing those contentions, applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of certain claims in view of Barany PCT, Boyce-Jacino, and Xu.

Conclusion

Applicant respectfully asserts that the application is in condition for allowance and requests issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, applicant requests that he call the undersigned at (650) 849-6620 to set up an interview.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 22, 2002

By: Charles E. Van Horn #40266
for M. Paul Barker
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